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EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

ART UNIT

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1753

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/961,249	Applicant(s) HASHIMOTO ET AL.
Examiner	Art Unit 1753	
ALEX NOGUEROLA		

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on ____.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-20 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-7,9-16,19 and 20 is/are rejected.

7) Claim(s) 8,17 and 18 is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 25 September 2001 is/are: a) accepted or b) objected to by the Examiner.

 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. ____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) The translation of the foreign language provisional application has been received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5,6 .

4) Interview Summary (PTO-413) Paper No(s). ____
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____

Claim Objections

1. Claims 1, 2, 5, 11, 15, and 16 are objected to because of the following informalities:
 - a) Claim 1, line 3: -- each of -- should be inserted between "to" and "which";
 - b) Claim 1, line 5: "electrode" should be replaced with -- electrodes --;
 - c) Claim 1, line 6: "flowing" should be -- flows --;
 - d) Claim 1, line 6: the second occurrence of "the" should be replaced with -- each --
 - e) Claim 1, line 7: "electrode." should be replaced with -- electrode when a voltage is applied between the nucleic acid fixed electrodes and the counter electrode. --;
 - f) Claim 2, line 2: "commonly" should be replaced with -- common --;
 - g) Claim 2, line 3: "provided" should be deleted;
 - h) Claim 2, line 3: "a" should be replaced with -- the --;
 - i) Claim 2, line 3: "number" should be deleted;
 - j) Claim 5, line 4: "to flow a test liquid" should be replaced with -- so that a test liquid can flow --;
 - k) Claim 11, line 4: "electrode" should be -- electrodes --;
 - l) Claim 15, line 4: "electrode" should be -- electrodes --;
 - m) Claim 15, line 6: "electrode." should be -- electrodes. --;
 - n) Claim 16, line 2: "electrode." should be -- electrodes. --;
 - o) Claim 16, line 3: -- each of -- should be inserted between "to" and "which"; and
 - p) Claim 18, line 4: "electrode." should be -- electrodes. --;
2. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. Claims 7, 14, and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant has not defined nor given an example of "a duplex chain cognitive body". Furthermore, this expression appears to have been created by Applicant and is unique to Applicant, as the examiner has not found another use of it in life science or biological encyclopedias or in a search of scientific journals. One with ordinary skill in the art cannot make or use the invention as claimed since the claims require use of an entity only known to Applicant. A cognitive body is a body that can think, learn, or solve problems. Is Applicant claiming using his detection sensor on a thinking (broadly defined) entity?

4. Claims 2, 6, 7, 10-15, 19, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a) Claim 2: the examiner does not see how this claim further structurally limits claim 1.

Claim 1 has only a counter electrode for the plurality of nucleic acid chain fixed electrodes and states that a current will flow between the nucleic acid chain fixed

electrodes and the counter electrode. So, claim 1 already implicitly requires the counter electrode to be common to the plurality of nucleic acid chain fixed electrodes;

b) Claim 6: this claim only provides for intended use of the detection sensor. How does this claim further structurally limit the detection sensor of claim 1?

c) Claim 7: this claim only provides for intended use of the detection sensor. How does this claim further structurally limit the detection sensor of claim 1?

d) Claim 10 recites the limitation "the probe nucleic acid chain" in line 3. There is insufficient antecedent basis for this limitation in the claim.

e) Claim 13: this claim only provides for intended use of the detection sensor. How does this claim further structurally limit the detection sensor of claim 10?

f) Claim 14: this claim only provides for intended use of the detection sensor. How does this claim further structurally limit the detection sensor of claim 13?

g) Claim 19: this claim only provides for intended use of the detection sensor. How does this claim further structurally limit the detection sensor of claim 16?

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h) Claim 20: this claim only provides for intended use of the detection sensor. How does this claim further structurally limit the detection sensor of claim 19?

5. Note that dependent claims will have the deficiencies of base and intervening claims.

Double Patenting

6. Claim 3 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 2.

When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). If the counter electrode is common to plurality of nucleic acid chain fixed electrodes as required by claim 2 then the counter electrode will also be for each of the plurality of nucleic acid chain fixed electrodes as required by claim 3.

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 8 of copending Application No. 09/995,614. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of claim 8 requires inserting a plurality of nucleic acid immobilized electrodes into a plurality vessels that have a counter electrode on the bottom of each vessel and subsequently applying a voltage across the nucleic acid immobilized electrodes and the counter electrodes. Thus, the method of claim 8 requires a nucleic acid detection sensor having a plurality of nucleic acid chain fixed electrodes to which a probe is fixed and a counter electrode arranged opposite to the nucleic acid chain fixed electrode, as provided by claim 1.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claim 6 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 8 of copending Application No. 09/995,614. Claim 1 from which claim 6 depends has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of claim 8 requires exposing the counter electrode and the nucleic acid chain fixed

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electrodes to a test sample and measuring the resulting electrochemical signal when a voltage is applied.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claim 9 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 11 of copending Application No. 09/995,614. Claim 1 from which claim 9 depends has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 11 provides for at least one reference electrode.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claim 10 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 12 of copending Application No. 09/995,614. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of claim 12 requires (a) inserting a plurality of nucleic acid immobilized electrodes into a plurality vessels that have reference electrode in each vessel and a counter electrode on the bottom of each vessel, and (b) subsequent to the inserting step, applying a voltage across the nucleic acid immobilized electrodes and the counter electrodes. Thus, the method of claim 12 requires a nucleic acid detection sensor having a

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plurality of nucleic acid chain fixed electrodes to which a probe is fixed, a counter electrode, and a plurality of reference electrodes, as provided by claim 10.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claim 13 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 12 of copending Application No. 09/995,614. Claim 10 from which claim 13 depends has been addressed above. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of claim 12 requires exposing the counter electrode and the nucleic acid chain fixed electrodes to a test sample and measuring the resulting electrochemical signal when a voltage is applied.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1-7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by the JPO computer translation of Hashimoto et al. (JP 10-146183), hereafter "Hashimoto".

Addressing claim 1, Hashimoto teaches a nucleic acid detection sensor comprising

a plurality of nucleic acid chain fixed electrodes to which a probe nucleic acid chain is fixed (electrodes 105 and 106 in Drawings 10(a) and 10(b)); and a counter electrode which is arranged opposite to the nucleic acid chain fixed electrode (electrode 104 in Drawings 10(a) and 10(b)), wherein a current flows between the counter electrode and the nucleic acid chain fixed electrode when a voltage is applied between the nucleic acid fixed electrodes and the counter electrode (paragraph [0059] of *Detailed Description*).

Addressing claim 2, as seen in Drawings 10(a) and 10(b) the counter electrode is common to the plurality of nucleic acid chain fixed electrodes to which a probe nucleic acid chain is fixed.

Addressing claim 3, as seen in Drawings 10(a) and 10(b) the counter electrode is for each of the plurality of nucleic acid chain fixed electrodes to which a probe nucleic acid chain is fixed.

Addressing claim 4, as seen in Drawings 10(a) and 10(b) the counter electrode and the nucleic acid chain fixed electrodes have flat planes as claimed.

Addressing claim 5, as seen in Drawings 10(a) and 10(b) a test liquid can flow between the counter electrode and the nucleic acid chain fixed electrodes.

Addressing claim 6, as noted in the rejection of claim 6 under 35 U.S.C. 112, second paragraph, this claim does not further structurally limit claim 1, so the rejection of claim 1 also applies to this claim. In any event, exposing the detection sensor of apparatus to a test liquid is discussed in paragraphs [0087]-[0092] of the *Detailed Description*, for example.

Addressing claim 7, as noted in the rejection of claim 7 under 35 U.S.C. 112, second paragraph, this claim does not further structurally limit claim 1, so the rejection of claim 1 also applies to this claim.

Addressing claim 9, a reference electrode is disclosed in paragraph [0113] of the *Detailed Description*.

15. Claims 1-3, 5-7, 16, and 19 are rejected under 35 U.S.C. 102(a) as being anticipated by Miyahara et al. (EP 1120646 A1), hereafter “Miyahara”.

Addressing claim 1, Miyahara teaches a nucleic acid detection sensor comprising a plurality of nucleic acid chain fixed electrodes to which a probe nucleic acid chain is fixed (electrodes 8 in Figure 2); and

a counter electrode which is arranged opposite to the nucleic acid chain fixed electrode (electrode 16 in Figure 2), wherein a current flows between the counter electrode and the nucleic acid chain fixed electrode when a voltage is applied between the nucleic acid fixed electrodes and the counter electrode (paragraph [0035]).

Addressing claim 2, as seen in Figure 2 the counter electrode is common to the plurality of nucleic acid chain fixed electrodes to which a probe nucleic acid chain is fixed.

Addressing claim 3, as seen in Figure 2 the counter electrode is for each of the plurality of nucleic acid chain fixed electrodes to which a probe nucleic acid chain is fixed.

Addressing claim 5, as seen in Figure 2 a test liquid can flow between the counter electrode and the nucleic acid chain fixed electrodes.

Addressing claim 6, as noted in the rejection of claim 6 under 35 U.S.C. 112, second paragraph, this claim doe not further structurally limit claim 1, so the rejection of claim 1 also applies to this claim. In any event, exposing the detection sensor of apparatus to a test liquid is discussed in paragraphs [0031]-[0046].

Addressing claim 7, as noted in the rejection of claim 7 under 35 U.S.C. 112, second paragraph, this claim doe not further structurally limit claim 1, so the rejection of claim 1 also applies to this claim.

Addressing claim 16, for the claimed limitations see the abstract and Figure 2 and Figures 4(a) – 4(c).

Addressing claim 19, as noted in the rejection of claim 6 under 35 U.S.C. 112, second paragraph, this claim does not further structurally limit claim 1, so the rejection of claim 1 also applies to this claim. In any event, exposing the detection sensor of apparatus to a test liquid is discussed in paragraphs [0031]-[0046].

Allowable Subject Matter

16. Claim 8, 17, and 18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

17. Claims 11, 12, and 15 would be allowable if rewritten to overcome the rejections under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

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18. The following is a statement of reasons for the indication of allowable subject matter:

- a) Claim 8 requires that the nucleic acid chain fixed electrodes and the counter electrode be mutually engaged comb electrodes. In copending application 09/995,614 the counter electrode, of unspecified shape, is located on the bottom of a vessel into which the nucleic acid chain fixed electrode, of unspecified shape, is lowered. In Hashimoto, the counter electrode and the nucleic acid chain fixed electrodes are comprise opposing conductive films. In Miyahara the counter electrode comprises a continuous band of conductive material around the upper portion of a measurement zone and the nucleic acid chain fixed electrodes comprise an array of dots of conductive material at the bottom of the measurement zone;
- b) Claim 11 requires that the nucleic acid chain fixed electrodes and the reference electrodes are engaged comb electrodes. In copending application 09/995,614 the reference electrodes, of unspecified shape, are located in the vessels into which the nucleic acid chain fixed electrodes, of unspecified shape, are lowered;
- c) Claim 12 requires "a reference resistor connected between an output side of the first amplifier and the reference potential." The claims of copending application 09/995,614 do not mention such a resistor. Although amplifiers are also not mentioned in the claims of copending application 09/995,614, to provide at least an amplifier to amplify the measurement signal from the reference electrode is known in the art;

- b) Claim 15 requires the counter electrode and the nucleic acid chain fixed electrodes to be formed on the same plane the counter electrode to be formed so as to surround the nucleic acid fixed chain electrodes. In copending application 09/995,614 the counter electrodes, of unspecified shape, are located on the bottom of the vessels into which the nucleic acid chain fixed electrodes, of unspecified shape, are lowered;
- c) Claim 17 requires providing a reference electrode for each of the nucleic acid chain fixed electrodes. Miyahara does not mention providing a reference electrode. While it may have been obvious to provide a single reference electrode, similar to the counter electrode, which is in the form of band running along the inner walls of the measurement zone, it would not have been obvious to provide a reference electrode for each nucleic acid chain fixed electrode. As seen in Figure 2, the nucleic acid chain fixed electrodes are in the form of a highly dense matrix of conductive spots. To provide a complementary matrix of reference electrodes would require significant redesign of the detection sensor; and
- d) Claim 18 requires the nucleic acid fixed electrodes and the counter electrode to be formed on the same plane. As seen in Figure 2 of Miyahara the counter electrode is in the form of band running along the inner walls of the measurement zone, above the matrix of nucleic acid fixed electrodes, which are on the bottom of the measurement zone.

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19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (703) 305-5686. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (703) 308-3322. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Alex Noguerola
Alex Noguerola

11/16/03

Primary Examiner

TC1753